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DOCKET NO.: C1039.70058US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Heather L. Davis et al.
Serial No.:	10/023,909
Confirmation No.:	8458
Filed:	December 18, 2001
For:	USE OF NUCLEIC ACIDS CONTAINING UNMETHYLATED CPG DINUCLEOTIDE AS AN ADJUVANT
Examiner:	Jeffrey S. Parkin
Art Unit:	1648

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 12th day of April, 2005.

Terrance M. Flynn

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

In response to the Final Office Action mailed January 13, 2005, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims that begins on page 2 of this Amendment.

Remarks begin on page 6 of this Amendment.

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Terrance M. Flynn

MAIL STOP AF
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Amendment and Exhibit A
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

Maria A. Trevisan, Reg. No.: 48,207
Wolf, Greenfield & Sacks, P.C.
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Telephone: (617) 646-8000

Docket No.: C1039.70058US00
Date: April 12, 2005
x04/13/05x

886862

In the Claims

Please replace all prior versions, and listings, of claims in the application with the following list of claims:

1. (Previously Presented) A method of inducing an antigen specific immune response in a subject, comprising:

administering to the subject in order to induce an antigen specific immune response an antigen and a combination of adjuvants, wherein the combination of adjuvants includes at least one oligonucleotide containing at least one unmethylated CpG dinucleotide and at least one non-nucleic acid adjuvant, wherein the non-nucleic acid adjuvant is a non-saponin immune stimulating adjuvant, wherein the combination of adjuvants is administered in an effective amount for inducing a synergistic adjuvant response, and wherein the oligonucleotide is 8-100 nucleotides in length and has at least one phosphate backbone modification.

2-4. (Cancelled)

5. (Previously Presented) The method of claim 1, wherein the immune stimulating adjuvant is selected from the group consisting of PCPP polymer, derivatives of lipopolysaccharides, MPL, MDP, t-MDP, OM-174 and *Leishmania* elongation factor.

6-7. (Cancelled)

8. (Original) The method of claim 1, wherein the combination of adjuvants is administered with a priming dose of antigen.

9. (Original) The method of claim 1, wherein the combination of adjuvants is administered with a boost dose of antigen.

10. (Original) The method of claim 8, wherein the subject is administered a boost dose of antigen and oligonucleotide containing at least one unmethylated CpG dinucleotide after the priming dose.

11. (Original) The method of claim 9, wherein the subject is administered a priming dose of antigen and oligonucleotide containing at least one unmethylated CpG dinucleotide before the boost dose.

12. (Original) The method of claim 1, wherein the oligonucleotide containing at least one unmethylated CpG dinucleotide has a sequence including at least the following formula:

$$5' X_1 X_2 CGX_3 X_4 3'$$

wherein C and G are unmethylated, wherein X_1X_2 and X_3X_4 are nucleotides.

13. (Original) The method of claim 12, wherein the 5' X_1 X_2CGX_3 X_4 3' sequence is a non-palindromic sequence.

14-19. (Cancelled)

20. (Original) The method of claim 12, wherein X_1X_2 are nucleotides selected from the group consisting of: GpT, GpG, GpA, ApA, ApT, ApG, CpT, CpA, CpG, TpA, TpT, and TpG; and X_3X_4 are nucleotides selected from the group consisting of: TpT, CpT, ApT, TpG, ApG, CpG, TpC, ApC, CpC, TpA, ApA, and CpA.

21. (Original) The method of claim 12, wherein X_1X_2 are selected from the group consisting of GpA and GpT and X_3X_4 are TpT.

22. (Original) The method of claim 12, wherein X_1X_2 are both purines and X_3X_4 are both pyrimidines.

23. (Original) The method of claim 12, wherein X_2 is a T and X_3 is a pyrimidine.

24. (Original) The method of claim 12, wherein the oligonucleotide is 8 to 40 nucleotides in length.

25. (Original) The method of claim 12, wherein the oligonucleotide is isolated.

26. (Original) The method of claim 12, wherein the oligonucleotide is a synthetic oligonucleotide.

27. (Original) The method of claim 1, wherein the subject is an infant.

28. (Original) The method of claim 1, wherein the antigen is derived from an infectious organism selected from the group consisting of a virus, bacterium, fungus and parasite.

29. (Original) The method of claim 1, wherein the antigen is a tumor antigen.

30. (Original) The method of claim 1, wherein the antigen is an allergen.

31. (Original) The method of claim 1, wherein the antigen is in the form of a crude extract.

32. (Original) The method of claim 1, wherein the antigen is in the form of a purified molecule including a protein or a polysaccharide.

33. (Original) The method of claim 1, wherein the antigen is in the form of a recombinant molecule including a protein, polypeptide, peptide or peptide mimic of a polysaccharide antigen.

34. (Cancelled)

35. (Original) The method of claim 1, wherein the non-nucleic acid adjuvant by itself gives a Th1 immune response (e.g., MPL) but when used in combination with the CpG oligonucleotide gives a stronger Th1 response.

36-98. (Cancelled)

REMARKS

Applicants respectfully request reconsideration. Claims 1-3 and 5-35 were previously pending in this application. By this amendment, Applicants are cancelling without prejudice or disclaimer 2, 3, 6-7, 1-19 and 34 which were previously withdrawn. Applicants are also cancelling claims 14. As a result, claims 1, 5, 8-14, 20-33 and 35 are pending for examination with claim 1 being an independent claim. No new matter has been added.

37 C.F.R. §198

Applicants thank the Examiner for the indication that the Information Disclosure Statement filed November 18, 2004 has been placed in the application file and the information referred to therein has been considered.

Rejection under 35 U.S.C. §112

The Examiner rejected claims 1, 5, 8-14, 20-33, and 35 under 35 U.S.C. §112 first paragraph as containing subject matter not described in the specification. According to the Examiner, the addition of the words "non-saponin" prior to the term "immune stimulating adjuvant" is new matter. Applicants disagree.

In support of the foregoing amendments, Applicants direct the Examiner's attention to In re Johnson, 558 Fed. 2d. 1008, CCPA 1977 (Copy attached as Exhibit A). The court in In re Johnson held that if a genus and a subgenus were disclosed, then a new claim covering the genus but excluding the subgenus was supported, as if this claim scope had been explicitly presented.

In the instant application, Applicants have disclosed a genus of compounds (immune stimulating adjuvants) which includes a species (saponins). In view of this disclosure Applicants' specification adequately supports a claim to a genus but excluding the subgenus.

Accordingly, withdrawal of the rejection of claims 1, 5, 8-14, 20-33 and 35 under 35 U.S.C. §112 is respectfully requested.

Rejection under 35 U.S.C. §112

The Examiner rejected claims 1, 5, 8-14, 20-33, and 35 under 35 U.S.C. §112, first paragraph as lacking enablement.

1. According to the Examiner, the "disclosure fails to provide adequate guidance pertaining to the structural requirements of any given ISS-ODN." According to the Examiner, "the disclosure fails to provide sufficient guidance pertaining to the composition and length of those sequences that produce a synergistic immune response when combined with another adjuvant." (Office Action, page 3).

Initially Applicants wish to point out again that the invention specifies CpG oligonucleotides, rather than ISS-ODN. It is Applicants' understanding that other investigators use the term ISS in a manner which is not always consistent with the use of CpG oligonucleotides by Applicants and as defined in the above-identified patent application. Thus, it is important to make a distinction.

The claims include a significant amount of structure, that the examiner has indicated is missing. For instance, claim 1 specifies that the CpG oligonucleotide has a prescribed length limitation (8-100 nucleotides) and a phosphate backbone modification and includes the critical CpG motif. Additionally, dependent claims 12-13 and 20-24 provide further narrowing limitations with respect to the structure of the CpG oligonucleotide. For instance, claim 21 narrows X_1X_2 to two possible choices of dinucleotide sequences and X_3X_4 to a single dinucleotide sequence. The Examiner has not addressed the reasons for rejecting a claim of such narrow scope.

As described in the response to the last office action, the claimed CpG oligonucleotides all have the common structural property of an unmethylated CpG dinucleotide. This class of oligonucleotides is known and has been described extensively in patents and patent applications. It is the unmethylated CpG dinucleotide that confers the immune stimulating properties on the oligonucleotide. It is now believed that CpG oligonucleotides act through a common cellular receptor, TLR9. It is believed that CpG oligonucleotides are recognized by TLR9 and that this leads to the promotion of an immune response in which a Th1 response is favored. It is this common mechanism that unifies the resultant immune response produced by CpG oligonucleotides.

Applicants have provided sufficient reasons for why one of skill in the art would expect the claimed class of CpG oligonucleotides to function in the manner set forth in the claims. The Examiner has not provided any evidence or adequate reasoning why one of skill in the art would doubt this assertion.

2. According to the Examiner, the "disclosure fails to provide adequate guidance pertaining to those immune stimulating adjuvants (e.g., saponins, MPL, MDP, etc.) that can reasonably be expected to produce a synergistic immune response when combined with another adjuvant." The Examiner has dismissed the Declaration of Dr. Davis submitted in response to the last office action, stating "while the declaration of Dr. Hunter (sic) provides some evidence for a synergistic immune response (e.g., CpG-1826, alum, and HBSag), it also demonstrates that many combinations of CpG-ODN, non-nucleic acid adjuvant, and immunogen were not synergistic." Applicants respectfully disagree.

The Examiner has either not reviewed the data presented in the Declaration of Dr. Davis or has misunderstood the data. The data provided therein demonstrate, as thoroughly described in the instant patent application, that the use of other immune stimulating adjuvants in combination with CpG-ODN results in a synergistic activation of the immune system. Specifically, these data demonstrate synergy between CpG-ODN and immune stimulating adjuvants consistent with the data presented in Example 2 of the specification.

The results presented in Exhibit 1 attached to the Declaration of Dr. Davis demonstrated that immune stimulating adjuvants including Montanide ISA 720 (Seppic Inc.), Freund's incomplete adjuvant (FIA), cholera toxin (CT), E. coli heat-labile toxin (LT), cholera toxin subunit B (CTB), the B subunit of Escherichia coli heat labile enterotoxin (LTB), and various detoxified LT (LTK63, LTE112K, LTS61F, LTR192G, or LTA69G), and MF-59 produced synergistic (e.g., more than additive) immune responses when combined with representative CpG-ODN including CpG-ODN 1826 (SEQ ID NO:86) and CpG-ODN 7909 (SEQ ID NO:77). The Examiner is respectfully requested to point out where the Declaration "demonstrates that many combinations of CpG-ODN, non-nucleic acid adjuvant, and immunogen were not synergistic," as asserted by the Examiner.

3. According to the Examiner, the "prior art is unpredictable and teaches that many putative ISS elements do not function in the manner desired and often fail to facilitate immune responses to the immunogen of interest."

The Examiner has provided absolutely no evidence in support of this statement and thus has not met his burden for making a prima facie case in support of the rejection.

Additionally, at least for the reasons presented under sub-heading number 1, Applicants assert that one of skill in the art would expect CpG oligonucleotides having variant structure to function according to the claimed methods.

4. According to the Examiner, the "claims are of considerable breadth and are not fully supported by the disclosure."

Applicants have provided strong evidence that the breadth of the claims is adequately supported by the disclosure. Applicants have provided guidance in the specification for the use of immune stimulating adjuvants. Immune stimulating adjuvants are described in detail on page 6 lines 2-4, and further on page 19 lines 12-22. Immune stimulating adjuvants are defined as "an adjuvant that causes activation of a cell of the immune system" and several representative examples are listed. Example 2 in the specification (page 53, line 30 – page 54 line 1) illustrates the synergistic effect of treatment with CpG-ODN and MPL, an immune-stimulating adjuvant. The corresponding data are shown in Figure 7.

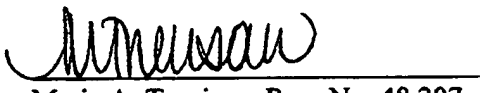
Accordingly, withdrawal of the rejection of claims 1, 5, 8-14, 20-33 and 35 under 35 U.S.C. §112 is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



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Docket No.: C1039.70058US00
Date: April 12, 2005
x04/13/05x

C

United States Court of Customs and Patent Appeals.
Application of Robert N. JOHNSON and Alford G. Farnham.
Patent Appeal No. 76-643.

June 16, 1977.

The Patent and Trademark Office Board of Appeals affirmed rejection of various claims in application, Serial No. 230,091, for "Polyarylene Polyethers," and appeal was taken. The Court of Customs and Patent Appeals, Markey, C. J., held that: (1) subject matter embraced by certain claims was definite and claims set out and circumscribed particular area with reasonable degree of precision and particularity; (2) claims were improperly rejected as broader than the enabling disclosure; (3) fact that applicant deleted certain compounds from protection sought and claimed less than full scope of disclosure did not render application insufficient under statute relating to specification.

Reversed.

Lane, J., dissented in part and filed opinion.

West Headnotes

[1] Patents ⇐101(6)
291k101(6) Most Cited Cases
Under statute providing that specification shall conclude with one or more claims particularly pointing out and distinctly claiming subject matter which the applicant regards as his invention, inquiry is whether claims do, in fact, set out and circumscribe particular area with reasonable degree of precision and particularity; definiteness of language employed must be analyzed, not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. 35 U.S.C.A. § 112.

[2] Patents ⇐99
291k99 Most Cited Cases
For purpose of statute relating to specification, undue breadth is not "indefiniteness." 35 U.S.C.A. § 112.

[3] Patents ⇐101(4)
291k101(4) Most Cited Cases
Claim language must be read in light of the specification as it would be interpreted by one of ordinary skill in the art. 35 U.S.C.A. § 112.

[4] Patents ⇐101(5)
291k101(5) Most Cited Cases
Subject matter embraced by claims relating to polyarylene polyether polymers
set out and circumscribed particular area with reasonable degree of precision and particularity, and thus rejection of claims under statute requiring specification to conclude with one or more claims particularly pointing out and distinctly claiming subject matter which applicant regarded as his invention was unwarranted. 35 U.S.C.A. § 112.

[5] Patents ⇐99
291k99 Most Cited Cases

[5] Patents ⇐101(1)
291k101(1) Most Cited Cases
It is the function of the specification, not the claims, to set forth the practical limits of operation of an invention; one does not look to the claims to find out how to practice the invention they define, but to the specifications. 35 U.S.C.A. § 112.

[6] Patents ⇐101(3)
291k101(3) Most Cited Cases
Specification as a whole must be considered in determining whether scope of enablement provided by specification is commensurate with scope of the claims. 35 U.S.C.A. § 112.

[7] Patents ⇐101(5)
291k101(5) Most Cited Cases
To provide effective incentives, claims must adequately protect inventors; to demand that the first to disclose shall limit his claims to what he has

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found will work or to materials which meet the guidelines specified for "preferred" materials in a process would not serve constitutional purpose of promoting the progress in the useful arts. 35 U.S.C.A. § 112.

[8] Patents ⇐99
291k99 Most Cited Cases
For purpose of claims relating to polyarylene polyether polymers, specification satisfied statutory requirements that specification contain concise written description of invention so as to enable any person skilled in the art to make and use the invention and that specification set forth best mode contemplated by inventor of carrying out his invention. 35 U.S.C.A. § 112.

[9] Patents ⇐109
291k109 Most Cited Cases
Fact that applicants excluded from original claims two species specifically disclosed in 1963 application did not render disclosure insufficient, under statute relating to specification, for "limited genus" claim where claim was otherwise entitled to benefit of 1963 filing date and where applicants had merely narrowed their claims to avoid having them read on a lost interference count. 35 U.S.C.A. § 112

[10] Patents ⇐98
291k98 Most Cited Cases
It is for the inventor to decide what bounds of protection he will seek. 35 U.S.C.A. § 112.
*1009 Robert C. Brown, New York City, Aldo J. Cozzi, Union City, N. J., attorneys of record, for appellants; James C. Arvantes, Arlington, Va., of counsel.

Joseph F. Nakamura, Washington, D. C., for the Commissioner of Patents; Henry W. Tarring, II, Washington, D. C., of counsel.

Before MARKEY, Chief Judge, and RICH, BALDWIN, LANE and MILLER, Judges.

MARKEY, Chief Judge.

This appeal is from the decision of the Patent and Trademark Office (PTO) Board of Appeals affirming the rejection under 35 U.S.C. ss 102 or 103 (the rejection also raises a written description issue under 35 U.S.C. s 112, first paragraph) of claims 1-9, 64, and 68-70 and the rejection under 35 U.S.C. s 112, first paragraph (enablement) and second paragraph (indefiniteness), of claims 64 and 68-72 in appellants' application No. 230,091 filed February 28, 1972 (the 1972 application) for "Polyarylene Polyethers." [FN1] The 1972 application is a continuation-in-part of three earlier applications, the earliest being application No. 295,519 filed July 16, 1963 (the 1963 application). We reverse.

FN1. Claims 10-54 and 65-67 stand allowed. A petition for reconsideration was denied by the board.

The Invention

The invention is in the field of polymer chemistry and more specifically relates to linear thermoplastic polyarylene polyether polymers composed of recurring units having the general formula O-E-O-E' where O represents an oxygen atom, [FN2] E represents the residuum of a dihydric phenol [FN3] compound, and E' represents the residuum *1010 of a benzenoid compound having one or more inert electron withdrawing groups [FN4] in the ortho [FN5] or para [FN6] positions to the valence bonds and where both E and E' are bonded to the ether oxygens through aromatic carbon atoms.

FN2. The -O- linkages in the general formula are called ether linkages.

FN3. A dihydric phenol is a type of aromatic organic compound in which two hydroxy (-OH) groups are attached directly to a benzene ring.

FN4. An electron withdrawing group is a substituent which withdraws electrons from the aromatic ring to which it is attached.

FN5. An aromatic ring bearing substituents on adjacent carbon atoms is called ortho substituted.

FN6. An aromatic ring bearing substituents on opposite carbon atoms is called para substituted.

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Appellants describe a method of synthesizing these polymers by reacting a double alkali metal salt of a dihydric phenol with a dihalobenzenoid compound in the presence of certain solvents under substantially anhydrous reaction conditions.

The 1972 application includes the following disclosure with respect to the electron withdrawing group found in E' and in the E' precursor compound, that is, in the compound which is the predecessor of E' in the above general formula (we have designated paragraphs (A) and (B) and have added emphasis thereto):

> Any electron withdrawing group can be employed as the activator group in these compounds. It should be, of course, inert to the reaction, but otherwise its structure is not critical. Preferred are the strong activating groups such as the sulfone group
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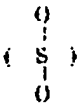
> 
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> bonding two halogon substituted benzenoid nuclei as in the 4,4'- dichlorodiphenyl sulfone and 4,4'-difluorodiphenyl sulfone, although such other strong withdrawing groups hereinafter mentioned can also be used with equal ease.

The more powerful of the electron withdrawing groups give the fastest reactions and hence are preferred. It is further preferred that the ring contain no electron supplying groups on the same benzenoid nucleus as the halogen; however, the presence of other groups on the nucleus or in the residuum of the compound can be tolerated. Preferably, all of the substituents on the benzenoid nucleus are either hydrogen (zero electron withdrawing), or other groups having a positive sigma * value, as set forth in J.F. Bunnett in Chem.Rev. 49 273 (1951) and Quart.Rev., 12, 1 (1958). See also Taft, Steric Effects in Organic Chemistry, John Wiley & Sons (1956), chapter 13; Chem.Rev., 53, 222; JACS, 74, 3120; and JACS, 75, 4231. [FN7]

> FN7. Appellants' brief specifically refers to one of the publications cited (Chem.Rev., 53, 222 (1953)) and states that its author (Jaffe) defines the sigma * value as a "special substituent constant" for the "Hammett equation" which is an empirically derived formula intended to show a general quantitative relation between the nature of a given substituent and the reactivity of a side chain. Thus, sigma * values are based on experimental data and they measure the "activation energy" of a given substituent (electron withdrawing group).

The electron withdrawing group of the dihalobenzenoid compound can function either through the resonance of the aromatic ring, as indicated by those groups having a high sigma * value, i.e., above about ⇦0.7 or by induction as in perfluoro compounds and like electron sinks.

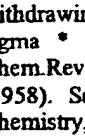
(A)

Preferably the activating group should have a high sigma * value, preferably above 1.0, although sufficient activity to promote the reaction is evidenced in those groups having a sigma value above 0.7, although the reaction rate with such a low powered electron withdrawing group may be somewhat low.

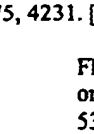
The activating group can be basically either of two types:

(a) monovalent groups that activate one or more halogens on the same ring as a nitro group, phenylsulfone, or alkylsulfone, cyano, trifluoromethyl, nitroso, and hetero nitrogen as in pyridine.

*1011 (b) divalent group (sic) which can activate displacement of halogens on two different rings, such as the sulfone group



; the carbonyl group



; the vinyl group

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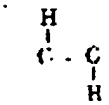
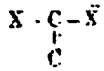


; the sulfoxide group

; the azo-group-N = N-; the saturated fluorocarbon groups -CF sub2 CF sub2 -; organic phosphine oxides

; where R is a hydrocarbon group, and the ethylidene group



where X can be hydrogen or halogen or which can activate halogens on the same ring such as with difluorobenzoquinone, 1,- 4- or 1,5- or 1,8-difluoroanthranquinone.

(B)

Those skilled in the art will understand that a plurality of electron withdrawing groups may be employed if desired, including electron withdrawing groups having a sigma * value below about ⊂=0.7 provided the cumulative sigma * influence on each of the reactive halogen groups of the halobenzenoid compound is at least about ⊂=0.7.

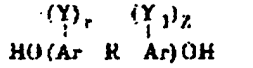
The Disclosure and Prosecution History of the 1963 Application

To understand the written description issue in this appeal, it is necessary to summarize the disclosure and prosecution history of the 1963 application. The 1963 application described (and claimed) in haec verba a genus of polymers as defined by the above general formula. That application stated:

> The high molecular weight polyarylene polyethers of the present invention are the linear thermoplastic reaction products of an alkali metal double salt of a dihydric phenol and a dihalobenzenoid compound. Characteristically, this polymer has a basic structure composed of recurring units having the formula
> -O-E-O-E'-
> wherein E is the residuum of the dihydric phenol and E' is the residuum of the benzenoid compound, both of which are valently bonded to the ether oxygen through aromatic carbon atoms, as hereinafter more fully discussed. Polymers of this type exhibit excellent strength and toughness properties as well as outstanding thermal, oxidative and chemical stability.

The 1963 application then discussed the identity of E and the E' precursor compound, that is, the compound which is the predecessor of E in the general formula. It stated:

> The residuum E of the dihydric phenol of these alkali metal salts is not narrowly critical. It can be, for instance, a mononuclear phenylene group as results from hydroquinone and resorcinol, or it may be a di- or polynuclear residuum. Likewise it is possible that the residuum be substituted with other inert nuclear substituents such as halogen, alkyl, alkoxy and like inert substituents.
>
> * * *
>
> Such dinuclear phenols can be characterized as having the structure:



wherein Ar is an aromatic group and preferably is a phenylene group, Y and Y subl can be the same or different inert substituent groups as alkyl groups having from 1 to 4 carbon atoms, halogen atoms, i. e. fluorine, chlorine, bromine or iodine, or alkoxy radicals having from 1 to 4 carbon atoms, r and z are integers having a value from 0 to 4, inclusive, and R is representative of a bond between aromatic carbon atoms as in dihydroxydiphenyl, or is a divalent radical, including for example, inorganic radicals as

,-O-, -S-, -S-S-, -SO2-, and divalent organic hydrocarbon radicals such as alkylene, alkylidene, cycloaliphatic, or the

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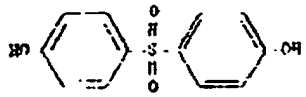
*1012 halogen, alkyl, aryl or like substituted alkylene, alkylidene and cycloaliphatic radicals as well as alkalicyclic, alkarylene and aromatic radicals and a ring fused to both Ar group[s].

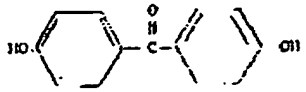
The application then mentioned by name some fifty specific dihydric dinuclear phenol (bisphenol) compounds which could be the - E precursor compound. The application further stated:

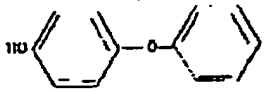
A preferred form of the polyarylene polyethers of this invention are those prepared using the dihydric polynuclear phenols of the following four types, including the derivatives thereof which are substituted with inert substituent groups

(a) 

in which the R group represents hydrogen, lower alkyl, lower aryl and the halogen substituted groups thereof, which can be the same or different.

(b) 

(c) 

(d) and 

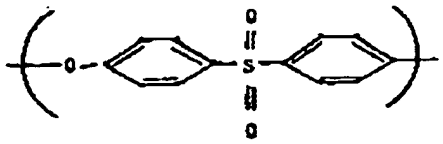
Turning to the identity of the E' precursor compound, the application stated:

Any dihalobenzenoid compound or mixture of dihalobenzenoid compounds can be employed in this invention which compound or compounds has the two halogens bonded to benzene rings having an electron withdrawing group in at least one of the positions ortho and para to the halogen group. The dihalobenzenoid compound can be either mononuclear where the halogens are attached to the same benzenoid ring or polynuclear where they are attached to different benzenoid rings, as long as there is the activating electron withdrawing group in the ortho or para position of that benzenoid nucleus.

The 1963 application also included a discussion of the electron withdrawing group that was substantially the same as the paragraphs quoted above from the 1972 application.

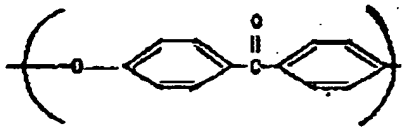
The 1963 application contained twenty-six "examples" disclosing in detail the physical and chemical characteristics of fifteen species of polyarylene polyethers. One of the species was the polymer composed of these recurring structural units (which we designate as species (1)): [FN8]

FN8. The -SO 2- linking group in species (1) is called a sulfone group.

[1] 

Another species disclosed was the polymer composed of these recurring structural units (which we designate as species (2)): [FN9]

FN9. The -CO- linking group in species (2) is called a carbonyl group.

[2] 

Appellants' 1963 application became involved in a three-party interference [FN10] which resulted in an award of priority adverse to appellants from which they did not appeal. [FN11] The sole count of the interference recited species (1).

FN10. Interference No. 95,807, declared February 17, 1967.

FN11. Another party did appeal. See Vogel v. Jones, 486 F.2d 1068, 179 USPQ 425 (Cust. & Pat.App.1973).

*1013 After their involvement in the interference

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ended, appellants filed the 1972 application, and they sought broad claims which would at the same time exclude the subject matter of the lost count.

The Claims

Claim 1, now on appeal, is illustrative of the group of claims (claims 1-9, 64, and 68-70) which seek to exclude the subject matter of the lost count and which are involved in the 35 U.S.C. ss 102 or 103 rejection:

1. A substantially linear thermoplastic polyarylene polyether composed of recurring units having the general formula:

-(O-E-O-E')-

where E is the residuum of a dihydric phenol and E' is the residuum of a benzenoid compound having an inert electron withdrawing group in one or more of the positions ortho and para to the valence bonds having a sigma * value above about ⇐0.7, and where both of said residuum (sic, residua) are valently bonded to the ether oxygens through aromatic carbon atoms with the provisos that E and E' may not both include a divalent sulfone group and may not both include a divalent carbonyl group linking two aromatic nuclei. (Emphasis added.)

The first "proviso" in claim 1, that "E and E' may not both include a divalent sulfone group," excludes species (1), the species of the lost count. The second "proviso," that "E and E' * * * may not both include a divalent carbonyl group," excludes species (2), which appellants state is "analogous" or "equivalent" to species (1). [FN12]

FN12. The provisos actually exclude more than species (1) and (2). For example, polymers similar to species (1) and (2) but having substituted ring structures are also excluded.

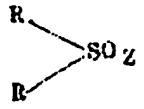
Claims 64 and 71 are illustrative of the group of claims (claims 64 and 68-72) rejected under 35 U.S.C. s 112, first and second paragraphs:

64. A substantially linear thermoplastic polyarylene polyether composed of recurring units having the general formula:

-(O-E-O-E')-

where E is the residuum of a dihydric phenol and E' is the residuum of a benzenoid compound having one or more inert electron withdrawing groups in at least one of the position (sic, positions) ortho and para to the valence bonds having a sigma * value sufficient to activate a halogen atom and where both of said residuum (sic, residua) are valently bonded to the ether oxygens through aromatic carbon atoms with the provisos that E and E' may not both include a divalent carbonyl group linking two aromatic nuclei. (Emphasis added.)

71. The process for preparing substantially linear polyarylene polyethers which comprises reacting substantially equimolar amounts of an alkali metal double salt of a dihydric phenol with a dihalobenzenoid compound having halogen atoms activated by an inert electron withdrawing group in at least one of the positions ortho and para to the halogen atom, under substantially anhydrous conditions and in the liquid phase of an organic solvent having the formula:



in which R represents a member of the group consisting of monovalent lower hydrocarbon groups free of aliphatic unsaturation on the alpha carbon atom and, when connected together represents a divalent alkylene group, and Z is an integer from 1 to 2 inclusive. (Emphasis added.)

The Rejections

The sole reference relied upon by the examiner and the board is:

*1014 Claims 1-9, 64, and 68-70 were rejected under 35 U.S.C. ss 102 or 103 as unpatentable in view of the Netherlands patent, which is a foreign-filed counterpart of appellants' 1963 application.

Before the PTO, appellants conceded that the invention was fully disclosed in the Netherlands patent. However, appellants contended that the claims are entitled to the benefit of the 1963 filing date under 35 U.S.C. s 120, [FN13] and therefore the Netherlands patent is not available as a prior art reference.

FN13. s 120. Benefit of earlier filing date

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> in the United States.
> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States by the same inventor shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. (Emphasis added.)

The examiner and the board were of the view that the claims are not entitled to the 1963 filing date because the presently claimed subject matter is not "described" in the 1963 application as required by the first paragraph of 35 U.S.C. s 112. [FN14] As explained by the board:

> FN14. s 112. Specification. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. (Emphasis added.)

The question determinative of the issue at hand is thus whether or not appellants are entitled to the filing date of their parent application Serial No. 295,519, i. e., July 16, 1963. An answer to this question quite obviously depends on what is the invention defined by the instant claims. It is the same as the one disclosed in (the) parent case or does it differ therefrom in a manner which precludes the instant claims from being afforded the filing date of the parent case?
Under the rationale of the CCPA as set forth in In re Welstead, 463 F.2d 1110, 59 CCPA 1105, 174 USPQ 449 (compare also In re Lukach et al., 442 F.2d 967, 58 CCPA 1233, 169 USPQ 795, and In re Smith ((I)), 458 F.2d 1389, 59 CCPA 1025, 173 USPQ 679), which we deem controlling, we are constrained to conclude that the present claims are not entitled to the filing date of appellants' parent case Serial No. 295,519. The claims at issue contain provisos that E and E' may not both include a divalent sulfone group and may not both include a divalent carbonyl group linking two aromatic nuclei. The artificial subgenus thus created in the claims is not described in the parent case and would be new matter if introduced into the parent case. It is thus equally "new matter," i. e., matter new to the present application for which no antecedent basis exists in the parent case. Consequently, appellants are not entitled to rely on the filing date of their parent case to support a new subgenus for which no basis exists in the parent case. The reason why appellants now limit their claims to exclude those species eliminated by the provisos, i. e., loss in an interference, is manifestly immaterial.
Having reached the conclusion that appellants are not entitled to the filing date of their parent case for the subject matter defined by the present claims which delineate a new subgenus not described in the parent case, it follows that the Netherlands patent is a valid reference which, by appellants' own admission, fully meets the claims.
The indicated rejection of claims 1-9, 64 and 68-70 under 35 U.S.C. 102 as unpatentable over the Netherlands patent is thus affirmed. The alternative reliance by the Examiner on Section 103 is inconsequential, Section 102 of the statute being the epitome of Section 103. In *1015 re Pearson, (Cust. & Pat.App.), 494 F.2d 1399, 181 USPQ 641.

Claims 64 and 68-72 were rejected under 35 U.S.C. s 112, first and second paragraphs. In his Answer, the examiner stated that the claims were rejected under s 112, first paragraph, for "being broader than the enabling disclosure" and under s 112, second paragraph, [FN15] for being "broader than the express limitations disclosed as defining the invention." The examiner said the "specific deficiencies of the claims and disclosure" are that the expression "to activate a halogen" (claim 64) is "indefinite" because "it does not specify toward what the activation is" and that "(t)he express disclosure is clearly limited to the sigma * value recited in claim 1, for example: see ((A) and (B))."

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> FN15. s 112. Specification.
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

In affirming the examiner on these rejections, the board stated:

> Further, claims 64 and 68-72 stand finally rejected under 35 U.S.C. 112 as being broader than the enabling disclosure (first paragraph) and broader than the express limitations disclosed as defining the invention (paragraph two).
> It is the Examiner's position that "to activate a halogen atom" (claim 64) is indefinite and that the disclosure also is limited to dihalobenzenoid compounds not broadly merely "activated by an inert electron withdrawing group". (claims 68-72) but the activation must have a sigma * value above about ⇐0.7.
> We agree with this rejection. The specification makes it quite clear that a minimum sigma * activation value of the halogen atoms is required (note especially ((A))) and an undefined sigma * value thus lacks the requisite preciseness commensurate with the enablement of the disclosure.

OPINION

I. The Rejections of Claims 64 and 68-72 under s 112

Claims 64 and 68-72 were rejected under both the first and second paragraphs of 35 U.S.C. s 112.

[1] We begin with the rejections under the second paragraph of s 112. As stated in In re Moore, 439 F.2d 1232, 1235, 58 CCPA 1042, 1046-1047, 169 USPQ 236, 238 (1971):

> Any analysis in this regard should begin with the determination of whether the claims satisfy the requirements of the second paragraph. * * *
> This first inquiry therefore is merely to determine whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. It is here where the definiteness of the language employed must be analyzed not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. (Footnote omitted.)

The examiner's s 112, second paragraph, rejection was premised on the general ground that the claims are "broader than the express limitations disclosed as defining the invention" and on two specific grounds: (a) that the expression "to activate a halogen atom" is "indefinite" because "it does not specify toward what the activation is;" and (b) that "(t)he express disclosure is clearly limited to the sigma * value recited in claim 1, for example: see ((A) and (B))." The board affirmed and stated: "an undefined sigma * value thus lacks the requisite preciseness * * *." (Emphasis added.)

Ground (a) focuses on the specific phrase "to activate a halogen atom." But the language is found only in claim 64, not in claims 68-72. Claim 68 recites "a dihalobenzenoid compound having halogen atoms activated by an inert electron withdrawing group," and claims 71 and 72 have a similar recitation. (Claims 69 and 70 depend from *1016 claim 68.) Those recitations clearly specify "toward what the activation is," as the examiner would require. Ground (a), therefore, lacks merit with respect to claims 68-72.

[2] Product claim 64 [FN16] defines the complete polymer structure by describing the constituents partially in terms of their functions in the reaction and by their linkage into the end-product polymer. The specification provides further guidance on the meaning of the E' term:

> FN16. Claims 68-70 are product-by-process claims.

> It is seen also that as used herein, the E' term defined as being the "residuum of the benzenoid compound" refers to the aromatic or benzenoid residue of the compound after the removal of the halogen atoms on the benzenoid nucleus. (Emphasis added.)

It is also clear from the specification as a whole, that two keys to the polymerization reaction are inert electron withdrawing groups particularly positioned on the benzenoid nucleus and a cumulative sigma * value attributable to those withdrawing groups which is sufficient to activate a halogen atom on that nucleus. If the sigma * value

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is not sufficient to activate a halogen atom on the benzenoid nucleus, the reaction will not take place and the polymer will not be made. See In re Angstadt, 537 F.2d 498, 190 USPQ 214 (Cust. & Pat.App.1976). The specification adequately details which sigma * values are sufficient to carry out the reaction, and any person skilled in the art would immediately recognize from the above-quoted portion of the disclosure or the specification as a whole that the halogen atom mentioned in claim 64 was on the benzenoid nucleus prior to the reaction. It is clear that those skilled in the art would have no trouble ascertaining whether any particular polymer falls within the scope of claim 64. See In re Goffe, 526 F.2d 1393, 188 USPQ 131 (Cust. & Pat.App.1975). The questioned limitation is merely surplusage, since the claim would be definite with or without it. [FN17]

FN17. We do not speculate on whether or not the claim would be unduly broad if the questioned limitation were removed. But undue breadth is not indefiniteness. In re Borkowski, 422 F.2d 904, 57 CCPA 946, 164 USPQ 642 (1970). This claim is definite either with or without the phrase "to activate a halogen atom."

[3][4] The point made by the board, that "an undefined sigma * value" lacks "preciseness," is also unsound. [FN18] Claim language must be read in light of the specification as it would be interpreted by one of ordinary skill in the art. In re Moore, supra. As pointed out above, those skilled in the art will be able to determine immediately from appellants' detailed specification what level of activation (i. e., sigma * value) is necessary to practice the invention. Cf. In re Mattison, 509 F.2d 563, 184 USPQ 484 (Cust. & Pat.App.1975). We conclude that the subject matter embraced by claims 64 and 68-72 is definite and that the claims set out and circumscribe a particular area with a reasonable degree of precision and particularity. In re Angstadt, supra; In re Skoll, 523 F.2d 1392, 187 USPQ 481 (Cust. & Pat.App.1975); In re Watson, 517 F.2d 465, 186 USPQ 11 (Cust. & Pat.App.1975); In re Moore, supra. Therefore, the rejection of claims 64 and 68-72 under the second paragraph of 35 U.S.C. s 112 is reversed.

FN18. In re Merat, 519 F.2d 1390, 186 USPQ 471 (Cust. & Pat.App.1975), cited be the Solicitor, affirmed a s 112, second paragraph, rejection because the same word ("normal") was used in the claims in one sense and in the specification in a different sense, thus rendering the claims indefinite. There is nothing akin to the Merat situation here.

The examiner's general ground and his ground (b) raise a lack of enablement issue properly arising under the first, not the second, paragraph of s 112. Ground (b) simply supplies the examiner's reasoning in support of the rejection of the claims under s 112, first paragraph, as "broader than the enabling disclosure."

As appellants state, the crux of this lack of enablement rejection is that although the specification describes how the halogen atoms bonded to the diahalobenzenoid compound (the E' precursor compound) must be activated in order for polymerization to occur, *1017 the claims at issue do not recite a numerical definition of the degree of activation (a minimum sigma * value) required from the electron withdrawing group. The PTO position is that the claims must recite a minimum sigma * value in order to conform the scope of the claims to the scope of enablement provided by the specification. The PTO relies on statements (A) and (B) to prove that the scope of enablement provided by the specification is not commensurate with the scope of the claims.

[5] First, we note that it is the function of the specification, not the claims, to set forth the "practical limits of operation" of an invention. In re Rainer, 305 F.2d 505, 509, 49 CCPA 1243, 1248, 134 USPQ 343, 346 (1962). One does not look to claims to find out how to practice the invention they define, but to the specification. In re Roberts, 470 F.2d 1399, 1403, 176 USPQ 313, 315 (Cust. & Pat.App.1973); In re Fuetterer, 319 F.2d 259, 50 CCPA 1453, 138 USPQ 217 (1963).

[6] Second, we note that the specification as a whole must be considered in determining whether the scope of enablement provided by the specification is commensurate with the scope of the claims. In re Moore, supra, 439 F.2d at 1235, 58 CCPA at 1047, 169 USPQ at 238-39.

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The present specification includes broad statements such as: "Any electron withdrawing group can be employed as the activator group in these compounds." The specification also discusses preferred embodiments, alternative embodiments, and the practical limits of operation.

Statement (A) describes preferred embodiments and practical limits of operation. It says that electron withdrawing groups having a high sigma * value ("preferably above 1.0") are preferred and that the practical limit of operation of the polymerization reaction is reached when the electron withdrawing group has a sigma * value of 0.7 (at that value the reaction rate "may be somewhat low").

Statement (B) describes an alternative embodiment ("a plurality of electron withdrawing groups") and the practical limit of operation for this embodiment. It states that the cumulative sigma * influence should be "at least about ⟸ 0.7."

[7][8] The PTO would limit appellants to claims reciting a sigma * value of at least 0.7. This view is improper because it requires the claims to set forth the practical limits of operation for the invention and it effectively ignores the scope of enablement provided by the specification as a whole. As we said in In re Goffe, 542 F.2d 564, 567, 191 USPQ 429, 431 (Cust. & Pat.App.1976):

> (T)o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts. See In re Fuetterer, 319 F.2d 259, 265, 50 CCPA 1453, 1462, 138 USPQ 217, 223 (1963). (Footnote omitted.)

The rejection of claims 64 and 68-72 under the first paragraph of 35 U.S.C. s

112 is reversed. II. The Rejection of Claims 1-9, 64, and 68-70 Under s 102 or s 103, Raising Issues Under s 112 and s 120

[9] We are convinced that the invention recited in claim 1 is "disclosed in the manner provided by the first paragraph of section 112" in the 1963 application and that claim 1 is therefore entitled to the benefit of the 1963 filing date. [FN19] The only inquiry is whether, after exclusion from the original claims of two species specifically disclosed in the 1963 application, the 1963 disclosure *1018 satisfies s 112, first paragraph, for the "limited genus" [FN20] now claimed.

> FN19. Appellants have not argued the claims separately, thus, claims 2-9, 64, and 68-70 stand or fall with claim 1.
>
> FN20. Appellants refer to the subject matter recited in claim 1 as a "limited genus." The board called it an "artificial subgenus." We use appellants' terminology. Whatever the label, the issue is the same.

While the board found that "no antecedent basis exists in the parent case" for the "limited genus" in claim 1, we see more than ample basis for claims of such scope. The 1963 disclosure is clearly directed to polymers of the type claimed. Fifty specific choices are mentioned for the E precursor compound, a broad class is identified as embracing suitable choices for the E' precursor compound, and twenty-six "examples" are disclosed which detail fifteen species of polyarylene polyethers. Only fourteen of those species and twenty-three of the "examples" are within the scope of the claims now on appeal. Two of the many choices for E and E' precursor compounds are deleted from the protection sought, because appellant is claiming less than the full scope of his disclosure. But, as we said in In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (Cust. & Pat.App.1976):

> Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable.

[10] It is for the inventor to decide what bounds of protection he will seek. In re Saunders, 444 F.2d 599, 607, 58 CCPA 1316, 1327, 170 USPQ 213, 220 (1971). To deny appellants the benefit of their grandparent application in this case would, as this court said in Saunders :

> * * * let form triumph over substance,

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substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed.

The board cited as "controlling" the decisions of this court in In re Welstead, 463 F.2d 1110, 59 CCPA 1105, 174 USPQ 449 (1972); In re Lukach, 442 F.2d 967, 58 CCPA 1233, 169 USPQ 795 (1971); and In re Smith, 458 F.2d 1389, 59 CCPA 1025, 173 USPQ 679 (1972). Those decisions, because of important factual distinctions, are not controlling.

In Welstead the applicant was attempting to introduce into his claims a new subgenus where " * * * the specification * * * contained neither a description * * * of the (subgenus) * * * nor descriptions of the species thereof amounting in the aggregate to the same thing * * *." Welstead conceded the absence from his disclosure of compounds of the "second type" within the new subgenus. Welstead is thus clearly distinguishable from the present case, in which appellants' grandparent application contains a broad and complete generic disclosure, coupled with extensive examples fully supportive of the limited genus now claimed. Indeed, Welstead might have well been cited by the board in support of a decision contrary to that reached, in view of what this court there implied concerning the possibility that "descriptions of species amounting in the aggregate to the same thing" may satisfy the description requirements of 35 U.S.C. s 112, paragraph one.

Similarly, in Lukach we noted that " * * * the grandparent application here does not disclose any defined genus of which the presently claimed copolymers are a subgenus." That is not the fact here. Appellants' grandparent application clearly describes the genus and the two special classes of polymer materials excluded therefrom.

In Smith the applicant sought the benefit of his prior application for a broadened generic claim, replacing the claim limitation "at least 12 carbon atoms * * * " with a new limitation calling specifically for 8 to 36 carbon atoms, where there was no disclosure of either the range itself or of a sufficient number of species to establish entitlement to the claimed range. Appellants, in contrast to the applicant in Smith, are narrowing their claims, and the full scope of the limited genus now claimed is supported in appellants' earlier application, generically and by specific examples.

*1019 The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of s 112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute. All that happened here is that appellants narrowed their claims to avoid having them read on a lost interference count.

The board indicated that "it is manifestly immaterial" why appellants limited their claims. Though it is true that insufficiency under s 112 could not be cured by citing the causes for such insufficiency, it is not true that the factual context out of which the question under s 112 arises is immaterial. Quite the contrary. Here, as we hold on the facts of this case, the "written description" in the 1963 specification supported the claims in the absence of the limitation, and that specification, having described the whole, necessarily described the part remaining. The facts of the prosecution are properly presented and relied on, under these circumstances, to indicate that appellants are merely excising the invention of another, to which they are not entitled, and are not creating an "artificial subgenus" or claiming "new matter."

In summary, and for the reasons discussed, the rejections of claims 64 and 68- 72 under s 112, first and second paragraphs, are reversed ; appellants' 1963 disclosure satisfied s 112, first paragraph, with respect to claims 1-9, 64, and 68-70 and appellants are, therefore, entitled to the benefit of their 1963 filing date under 35 U.S.C. s 120. The Netherlands patent is thus rendered unavailable as a prior art reference, and the rejection of the claims under 35 U.S.C. ss 102 or 103 is reversed.

REVERSED

LANE, Judge, dissenting in part.

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I would affirm the rejection of claims 64 and 68-72 under s 112, paragraphs 1 and 2, because the specification indicates that a minimum sigma value of ⇦ 0.7 is an essential requisite. These claims fail to recite this requisite, thus fail to define appellants' invention and are broader than the disclosure. I concur in reversing the rejection of claims 1-9.

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